

Inventor: Dale E. Koop  
Serial No.: 09/934,356  
Attny Dkt. No. 100698.0037US1

Art Unit: 3739  
Examiner: Ahmed M. Farah

“Anticipation under 35 USC § 102 requires the disclosure in a single piece of prior art of each and every limitation of a claimed invention...” *Rockwell International Corp. v. United States*, 147 F.3d 1358, 1363, 47 USPQ2d 1027, 1031 (Fed. Cir. 1998), (emphasis added).

O'Donnell, Jr. fails to disclose a “wound healing composition” as recited by claim 1 and disclosed in the application. A wound healing composition as defined by the specification includes a composition that amplifies the natural stimulation of growth or collagenesis caused by a wound. It is also taught that remodeling is further enhanced by the use of a transforming growth factor which accelerates the wound healing response. Growth factors that may participate in wound healing include, but are not limited to: platelet-derived growth factors (PDGFs); insulin-binding growth factor-1 (IGF-1); insulin-binding growth factor-2 (IGF-2); epidermal growth factor (EGF); transforming growth factor-.alpha. (TGF-.alpha.); transforming growth factor-.beta. (TGF-.beta.); platelet factor 4 (PF-4); and heparin binding growth factors one and two (HBGF-1 and HBGF-2, respectively).

Based on the failure to claim each and every element, claim 1 (and claims 2-3 by virtue of their dependence on claim 1) is not anticipated by O'Donnell, Jr.

#### **Claims 8-10**

The Office objected to claims 8-10 as being anticipated by O'Donnell, Jr. The applicant disagrees for the same reasons as stated above.

Claims 8-10 all require “a wound healing promoter composition”. O'Donnell, Jr. does not disclose such a composition as disclosed by the specification, and therefore claim 8-10 are novel over O'Donnell, Jr.

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**Claim Rejections – 35 U.S.C. § 103**

**Claims 4-6 and 11**

The Office rejected claims 4-6 and 11 as being obvious over O'Donnell, Jr. in view of Purchio et al. (US Patent 5599788) (Purchio). The applicant disagrees for the reasons stated below.

Claims 4-6 are dependent claims which are dependent on claim 1. Since claim 1 is novel over O'Donnell, Jr., as pointed out above, any dependent claims would also be novel. (see MPEP § 608.01 (n) and *In re Fritch*, 972 F.2d 1260, 1266; 23 USPQ2d 1780, 1784 (Fed. Cir. 1992) [*"dependent claims are non-obvious if the independent claims from which they depend are non-obvious..."*]).

With regard to claim 11, the applicant is not convinced that it would have been obvious to combine the teachings of O'Donnell, Jr. with Purchio. When the motivation to combine the teachings of the references is not immediately apparent, it is the duty of the examiner to explain why the combination of the teachings is proper. *Ex parte Skinner*, 2 USPQ2d 1788 (Bd. Pat. App. & Inter. 1986). A statement of a rejection that includes a large number of rejections must explain with reasonable specificity at least one rejection, otherwise the examiner procedurally fails to establish a prima facie case of obviousness. *Ex parte Blanc*, 13 USPQ2d 1383 (Bd. Pat. App. & Inter. 1989) (Rejection based on nine references which included at least 40 prior art rejections without explaining any one rejection with reasonable specificity was reversed as procedurally failing to establish a prima facie case of obviousness.).

Yes, Purchio teaches use of a protein to accelerate wound healing, but this is not in conjunction with non-invasive collagen remodeling. The portion of the specification which the examiner has referred the applicant to (Col. 4, lines 58-60) teaches that "Gene therapy using H3 may be combined with conventional chemotherapy and radiation treatment to increase the overall treatment efficacy." Gene therapy is not the same or a related field. "In order to rely on a reference as a basis for rejection of an applicant's invention, the reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem

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with which the inventor was concerned." In re Oetiker, 977 F.2d 1443, 1446, 24 USPQ2d 1443, 1445 (Fed. Cir. 1992). See also In re Deminski, 796 F.2d 436, 230 USPQ 313 (Fed. Cir. 1986); In re Clay, 966 F.2d 656, 659, 23 USPQ2d 1058, 1060-61 (Fed. Cir. 1992).

Here, the problem that is being solved by applying a growth factor is the acceleration of collagenesis. In fact, claim 11 recites that the growth factor is applied "such that collagenesis... is accelerated." Purchio is not in the same field or even reasonably pertinent to collagenesis.

### **Claim 7**

The Office considers claim 7 to be obvious over Tankovich et al. (U.S. Patent 5817089) (Tankovich) in view of Purchio. The applicant respectfully disagrees for the following reasons.

Again, Purchio is non-analogous art which is not in the field of endeavor of the present invention or even reasonably pertinent to the problem being solved by the present claims. Additionally, the examiner has not provided any motivation to combine the teachings of the references, and any such combination is done using hindsight, which is improper.

### **Objections to the drawings**

Objections to the drawings have been noted. The applicant will submit amended drawings upon notification of allowance.